



## **Turkey Adopts European Union Industrial Directives (CE Marking)**

### **Turkey Adopts the CE Mark**

The Government of Turkey's Undersecretariat for Foreign Trade announced the implementation of twenty-three European Union industrial directives, which would affect an estimated 70% of the manufactured products imported into Turkey. The Undersecretariat for Foreign Trade has adopted the EU's Low Voltage Directive, the Simple Pressure Vessels Directive, the Gas Appliances Directive, the Hot Water Boilers Directive, the EMC, the Machinery Directive, the Civil Explosives Directive, the Weighing Instruments Directive, the Equipment and Protective Systems Intended in Explosive Atmospheres Directive, the Lifts Directive (elevators), the Household Refrigerator/Freezer Directive, the Pressure Equipment Directive, the Noise Emission Directive, the Energy Efficiency for Ballast for Fluorescent Lighting Directive, the Active Implantable Medical Device Directive, the Medical Device Directive, the In Vitro Diagnostics Device Directive, the Toy Directive, the Recreational Water Craft Directive, the Construction Equipment Directive, the Personal Protective Equipment Directive, the Radio and Telecommunications Terminal Equipment Directive and the Cableway Directive (ski lifts and gondolas).

Equipment meeting the directive definition of products needing to conform to EU technical regulations must have evidence of meeting the requirements either through verified laboratory testing conducted by an EU approved notified body or by manufacturer's self-declaration if the directive dictates. Companies selling to the Turkish market must submit evidence of conformity compliance (CE Mark) either by providing a notarized/consularized conformity certificate from a notified body or a manufacturer's issued certificate of conformity, which declares compliance of all relevant standards and directive annexes.

The CE Mark was established by the European Union to ensure the free circulation of products in Europe. The directives that were entered into effect under a system called the "New Approach," were established to ensure, health and safety, consumer and environmental protection. The "New Approach" identifies level of risk and hazard. Annexes to the various EU directives will specify levels of risk and types of products that would need to be either certified by a notified body or if the product can be certified by the manufacturer as conforming to the particular directive(s). The EU's laws and regulations made it compulsory to comply with the directives when goods are sold in the territory of the European Union and the European Economic Area (EEA). Companies must show evidence of product compliance by maintaining or presenting a technical file that includes product specifications,

technical drawings and standards applied per the appropriate directives and corresponding annexes.

However, if there is no applicable directive for a particular product, then Turkey is obliged to allow the import of products manufactured in the United States pursuant to Turkish national regulations. This is known as the “Reciprocal Recognition Principle.”

#### Needing Time to Adjust

Since the adoption of the twenty-three European Union technical regulations, which equate to the CE Mark, significant confusion has resulted in substantial delays in Customs clearance formalities and companies not requiring the CE mark have been often asked for a Certificate of Conformity. Within the European Union Directives, the Commission authorizes member states the right to inspect manufactured goods if there is probable cause that either the manufactured product poses a potential hazard or the member state believes that despite certification of conformity, the product does not meet the European harmonized standard or the certification is suspect. Given this provision in EU product legislation and given the Turkish Customs Service need to adjust to the new regime, a European only bias has emerged in that all products of European origin that meet the requisite standards conformity have been allowed full access to the Turkish market. Many U.S. companies have complained that despite manufacturer’s self declaration or notified body certification of conformity, the Government of Turkey has often demanded Turkish Standards Institute (TSE) standards testing using the potential hazard provision of the regulations. In other instances, the Turkish Customs Service has demanded CE marking for products that do not fall under any of the twenty-three industrial standards adopted by the Turkish Republic. U.S. companies showing evidence of conformity and having appropriate documentation should be allowed immediate access to the Turkish market. If companies are having difficulties in clearing Turkish Customs and have the appropriate CE Mark, they should notify the Commercial Section at the U.S. Embassy in Ankara immediately at the contact information provided at the end of this report.

#### Delegation of Authority and Market Access

Once Turkey is able resolve the current customs clearance and documentary formality growing pains, it would be simpler for U.S. companies to export to Turkey when products conform to EU directives. In the case of the Active Implantable Devices Directive, the Medical Device Directive and the In Vitro Diagnostic Devices Directive, the Ministry of Health and the Turkish Standards Institute would no longer be involved in approving medical devices for sale to the Turkish market. An American company selling its Class II a/II b or Class III medical device would be allowed market access with a Certificate of Conformity issued by an EU accredited notified body. Medical device manufacturers producing Class I devices can self

certify conformity to the relevant EU directives. Likewise the Ministry of Industry would allow unhindered market access for the sixteen directives that were formerly under its jurisdiction. Many U.S. products have already been CE marked and are sold to the European market. Turkey's adoption and implementation of the EU directives should now afford the same access to the Turkish market.

#### CE Mark Enforcement

The Government of Turkey (GOT) has directed the Turkish Customs Service to ensure that all imported products that fall within a particular EU industrial directive must show conformity to the standard. The GOT has further announced that its domestic industry would have an additional six months in order to meet the CE Mark requirements.

#### U.S. Embassy Contacts

The United States Embassy's Commercial Section has been assisting U.S. companies, which meet EU directives conformity, in having products clear Turkish Customs as expeditiously as possible. The Commercial Section is also working to have the Government of Turkey accept CE conformity certification from U.S. corporations or U.S.-based Notifying Bodies, without having U.S. companies face additional bureaucratic delays at customs and additional testing at the Turkish Standards Institute. For additional assistance in managing the new CE Mark regulations in Turkey, please contact Commercial Attaché Erik Hunt at [Erik.Hunt@mail.doc.gov](mailto:Erik.Hunt@mail.doc.gov).

For additional information on the European Union Directives and European standards, please contact Sylvia Mohr, Standards Specialist at the U.S. Mission to the European Union at [Sylvia.Mohr@mail.doc.gov](mailto:Sylvia.Mohr@mail.doc.gov).

#### CE Websites

[http://www.ita.doc.gov/td/tic/ce\\_mark/ceindex1.htm](http://www.ita.doc.gov/td/tic/ce_mark/ceindex1.htm)  
<http://ts.nist.gov/ts/htdocs/210/ncsci/export-eu.htm>  
[www.buyusa.gov/europeanunion](http://www.buyusa.gov/europeanunion)  
[http://europa.eu.int/comm/enterprise/index\\_en.htm](http://europa.eu.int/comm/enterprise/index_en.htm)  
[www.newapproach.org](http://www.newapproach.org)

#### Standards Websites

[www.cenorm.be](http://www.cenorm.be)  
[www.cenelec.org](http://www.cenelec.org)  
[www.etsi.org](http://www.etsi.org)  
[www.ansi.org](http://www.ansi.org)

